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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,776	12/12/2003	Mechthild Rieping	7601/80921	9536

66991 7590 12/27/2006
LAW OFFICE OF MICHAEL A. SANZO, LLC
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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/733,776

Applicant(s)

RIEPING, MECHTHILD

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 14, 15, 19, 20, 22, 23 and 25-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-37 is/are allowed.
- 6) ☒ Claim(s) 11, 14, 15, 19, 20, 22, 23, 25 and 28-34 is/are rejected.
- 7) ☒ Claim(s) 26 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Claims 11, 14-15, 19-20, 22-23, and 25-37 are pending in the application.
2. Applicant's amendment to the claims, filed on 25 October 2006, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims in accordance with 37 CFR 1.121(c). Applicant is reminded of the amendment practice according to 37 CFR 121(c), which requires a claim status identifier to be in a parenthetical expression. See particularly the identifier for the canceled claims.
3. Applicant's arguments filed on 25 October 2006 in response to the Office action mailed on 25 July 2006 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
4. The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

5. Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 has been amended to require "isolating said L-amino acid," where the claim previously recited "recovering or isolating said L-amino acid." Claims 22-23 are unclear in requiring that "said L-amino acid is recovered..." According to the instant

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response (p. 9, middle), it appears that applicant takes the position that the meaning of the term "isolating" is different from the meaning of the term "recovering." (See particularly the statement addressing claims 28-37 at p. 9, middle of the instant response, wherein it is stated, "[c]laims 28-37, are directed to processes in which the fermentation product of bacteria may be merely recovered, *i.e.*, isolation of amino acids is not required." However, it would appear from claims 22-23 that the terms are synonymous, *i.e.*, the term "isolating" is equivalent to "recovering." In view of this discrepancy, the meaning of the claims is unclear. It is suggested that applicant clarify the meaning of claims 22-23.

Claim Rejections - 35 USC § 112, First Paragraph

6. The new matter rejection of claims 11, 14-20, 22-23, 25-27, and 33 under 35 U.S.C. § 112, first paragraph, is withdrawn in view of applicant's showing of support for the limitation in claim 11 to recite "wherein said modification results in an increased production of L-threonine," namely p. 6, lines 17-21 of the specification, which states, "[i]t has been found that microorganisms of the Enterobacteriaceae family produce L-amino acids, in particular L-threonine, in an improved manner after attenuation, in particular elimination, of the *yjgF* gene or open reading frame (ORF) or alleles thereof."

Claim Rejections - 35 USC § 103

7. The rejection of claim(s) 11, 14-15, 19-20, 22-23, 25, and 28-34 under 35 U.S.C. 103(a) as being unpatentable over Volz (*Protein Sci* 8:2428-2437, 1999; cited in

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the IDS filed on 11/18/2004) in view of Enos-Berlage et al. (*J. Bacteriol* 180:6519-6528, 1998; cited in the IDS filed on 11/18/2004) is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant argues: 1) amended claims 11-27 now require the step of isolating an L-amino acid and since the cited references do not teach any relationship between the *yjgF* mutation and amino acid production, they would not render a process that included the step of isolating amino acids from a fermentation broth obvious and 2) amended claims 28-37 require that the amount of amino acid present in the recovered material be determined, a step that is not inherent in the teachings of the cited references.

Applicant's argument is not found persuasive. Regarding the amendment to claims 11-27, it is noted that claims 12-13, 16-18, 21, and 24 have been canceled and the rejection does not apply to claims 26-27. Thus, applicant's argument has been interpreted as addressing pending claims 11, 14-15, 19-20, 22-23, and 25.

The examiner maintains the position that the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention in view of the combination of cited references. It should be noted that there is no dispute there is motivation to combine the reference teachings and there is a reasonable expectation of success for making an *E. coli* with deletion of the *yjgF* gene and analyzing the resulting mutant by the method of Enos-Berlage et al. The Courts generally accept as fact an examiner's finding that is undisputed by applicant. See *In re Kunzmann*, 140 USPQ 235 (CCPA 1964). As such, the rejection satisfies the first two requirements of a *prima facie*

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case of obviousness according to MPEP 2143. The issue appears to be whether or not the method suggested by the cited references would have inherently taught the step of "isolating said L-amino acid."

In the previous Office action, the examiner made clear that the invention – regardless of whether the method requires "recovering" or "isolating" – is obvious in view of the combination of references. See particularly p. 10, lines 12-15 of the prior Office action, which states, "one would necessarily recover or isolate the L-amino acid in accordance with the claims" (emphasis added). However, based on remarks provided in applicant's response, there appears to be such a distinction between the terms "recovering" and "isolating" that by removing the term "recovering," the claimed invention is no longer obvious in view of the combination of references. (p. 9, first and second full paragraphs). However, it remains unclear as to how the term "isolating" rather than "recovering" in claim 11 distinguishes the claimed invention from the combination of references. In this case, one of ordinary skill in the art would recognize that the term "isolating" is not an absolute, but is a term of degree. MPEP 2111 states, "[d]uring patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification'" and "[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." In this case, the specification fails to provide a specific definition of the term "isolating" such that a skilled artisan would recognize the requisite degree of purity applicant intends as being encompassed by the term. The examiner has not interpreted the term "isolating" to infer isolating an L-amino acid to

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homogeneity, but has broadly and reasonably interpreted "isolating said L-amino acid" in claim 11 to include, e.g., removing cell debris, *i.e.*, unlysed cells and cell membranes, from a whole cell lysate (recovered from said enterobacterium) or isolating an aliquot of the culture or centrifuging the culture to isolate the liquid portion of the medium from whole cells and removing the liquid portion from the whole cells (recovered from said medium). This interpretation is supported by the specification (p. 4, lines 6-9), which discloses, "isolation of the desired L-amino acid, constituents of the fermentation broth and/or the biomass in its entirety or portions (>0 to 100 %) thereof optionally remaining in the product." Furthermore, it is noted that claims 22-23 use the term "recovered," suggesting that the terms "isolating" and "recovering" are synonymous. As such, removing cell debris from a cell lysate of an *E. coli* with deletion of the *yjgF* gene or isolating an aliquot of the culture or centrifuging the culture to isolate the liquid portion of the medium from whole cells and removing the liquid portion from the whole cells as suggested by the combination of references is *necessarily* a step of "isolating said L-amino acid."

While the examiner acknowledges the cited references do not teach any relationship between the *yjgF* mutation and amino acid production, according to MPEP 2112.I, "[t]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer" (citation omitted) and according to MPEP 2112.II, "[t]here is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the

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subject matter is in fact inherent in the prior art reference" (emphasis in original; citation omitted). Thus, at least for the reasons of record and the reasons stated above, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Regarding the amendment to claims 28-34, it is noted that claim 28 does not require determining the amount of amino acid. Instead claim 28 optionally recites, "isolating said L-amino acid" without requiring determining the amount of L-amino acid. As such, for the reasons of record and the reasons addressing the limitation of "isolating said L-amino acid" in claim 11 as set forth above, the invention of claims 28-34 would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Examiner Comment/Clarification

8. MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" (MPEP 8th Ed., October 2006 Revision at pp. 2100-176 and 2100-183) and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description."

Claims 28 (claims 29-34 dependent therefrom) and 35 (claims 36-37 dependent therefrom) recite the limitation of "determining the amount of said L-amino acid" (claim 28) or "determining the amount recovered" (claim 35). According to the instant response

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at p. 6, part II, “[s]upport for this and various analysis methods may be found on page 21, line 3-page 22, line 6.” The cited disclosure of the specification states, “[t]he temperature of the culture is usually 25.degree. C. to 45.degree. C., and preferably 30.degree. C. to 40.degree. C. Culturing is continued until a maximum of L-amino acids or L-threonine has formed. This target is usually reached within 10 hours to 160 hours. The analysis of L-amino acids can be carried out by anion exchange chromatography with subsequent ninhydrin derivation, as described by Spackman et al. (Analytical Chemistry 30:1190-1206 (1958)) or it can be carried out by reversed phase HPLC, as described by Lindroth et al. (Analytical Chemistry 51: 1167-1174 (1979)).”

MPEP § 2163 states that “there is no *in haec verba* requirement” for newly added claim limitations, only that “newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure” (MPEP 8th Ed., October 2005 Revision, p. 2100-175). According to the same section of the MPEP, “[t]he fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 156364, 19 USPQ2d at 1117.”

The disclosure relied on by applicant is directed to the “*analysis* of L-amino acids” (emphasis added). According to Stedman’s Online Medical Dictionary (www.stedmans.com), the term “analysis” in the context of the specification would appear to mean “a process by which the composition of a substance is determined” or “[t]he examination and study of a whole in terms of the parts composing it” (see

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Appendix A). In view of the definition of "analysis," the specification's disclosure would appear to relate to the analysis of the culture for L-amino acids and not the quantification of L-amino acids. However, it is noted that the cited specification disclosure references Spackman et al. as teaching a method for L-amino acid analysis. The reference of Spackman et al. teaches a method for chromatographic *quantification* of amino acids. As such, applicant's cited specification disclosure is considered to support the limitation of "determining the amount of said L-amino acid" (claim 28) or "determining the amount recovered" (claim 35).

Conclusion

9. Status of the claims:

Claims 11, 14-15, 19-20, 22-23, and 25-37 are pending.

Claims 11, 14-15, 19-20, 22-23, 25, and 28-34 are rejected.

Claims 26-27 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In view of the requirement in step b) of claim 35 to require "determining the amount [of L-amino acid] recovered," claims 35-37 appear to be in a condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

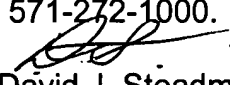
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656